PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 16 APR 2004

Applican	¥0.01.5=	onto file referen			WIPO PCI		
Applicant's or agent's file reference 0147-007.B.WO			FOR FURTHER	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)			
International application No. PCT/CH 03/00048		International filing da 23.01.2003	ate (day/month/year)	Priority date (day/month/year) 28.01.2002			
Internation A61M1		ent Classification (IPC) o	r both national classification	on and IPC			
Applicant DEBIO		S.A. ET AL.		·			
1. Th Au	 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 						
2. Thi	2. This REPORT consists of a total of 5 sheets, including this cover sheet.						
	been amended and are the basis for this report and/or sheets containing rectifications made before this Authority						
The	(see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 4 sheets.						
3. Thi	s report	contains indications	relating to the following	ı itame:			
1		Basis of the opinion		, items.			
Ü		Priority					
111		•	f opinion with regard to	novelty inventive	step and industrial applicability		
iV		Lack of unity of inver		moverty, miveriave	step and industrial applicability		
V	×	Reasoned statement		with regard to nove statement	elty, inventive step or industrial applicability;		
VI		Certain documents c	ited				
VII		Certain defects in the	international application	on			
VIII		Certain observations	on the international ap	plication			
Date of sub	Date of submission of the demand				n of this report		
25.08.2003				16.04.2004			
Name and mailing address of the international				Authorized Office			
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo ni				Kroeders, M	The Country of the Co		
	rax:	+31 70 340 - 3016		Telephone No. +3	1 70 340-1967		

. INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH 03/00048

I.	Basis	of	the	report
----	--------------	----	-----	--------

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	De	escription, Pages							
	1-8	3	as originally filed						
	Cla	Claims, Numbers							
	1-2	24	received on 16.03.2004 with letter of 16.03.2004						
	Dra	awings, Sheets							
	1/2	-2/2	as originally filed						
2.	Wit lan	Vith regard to the language , all the elements marked above were available or furnished to this Authority in the anguage in which the international application was filed, unless otherwise indicated under this item.							
	The	ese elements were a	vailable or furnished to this Authority in the following language: , which is:						
		the language of a ti	anslation furnished for the purposes of the international search (under Rule 23.1(b)).						
		the language of pul	olication of the international application (under Rule 48.3(b)).						
			anslation furnished for the purposes of international preliminary examination (under						
3.	Wit inte	h regard to any nucl ernational preliminary	eotide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:						
		contained in the inte	ernational application in written form.						
		filed together with the international application in computer readable form.							
		furnished subsequently to this Authority in written form.							
		furnished subsequently to this Authority in computer readable form.							
		The statement that in the international a	the subsequently furnished written sequence listing does not go beyond the disclosure application as filed has been furnished.						
		The statement that the listing has been furn	the information recorded in computer readable form is identical to the written sequence ished.						
	The	amendments have r	esulted in the cancellation of:						
		the description,	pages:						
		the claims,	Nos.:						
		the drawings,	sheets:						

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH 03/00048

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be a filed in the second ment and the s

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

- 6. Additional observations, if necessary:
- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

£1

Novelty (N)

Yes: Claims
1-24
No: Claims
Inventive step (IS)

Yes: Claims
1-24
No: Claims
Industrial applicability (IA)

Yes: Claims
Claims
Including 1-24
No: Claims
Including 1-24
No: Claims
-

2. Citations and explanations

see separate sheet



Re Item V

 \tilde{c}_{I}

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Document WO-A-9906082, which is considered to represent the most relevant state of the art, discloses (cf. page 6, line 19 to page 16, line 7):

automatic peritoneal dialysis sampling system (14, 30) adapted to automatically sample at specific time intervals volumetric fractions of dialysate contained in the peritoneum of a patient in order to improve the peritoneal dialysis for a given patient, wherein the peritoneal dialysis sampling system (14, 30) comprises a sampling container (30) and pumping means (P1) disclosed in combination with a series of valves (14, belonging to an automated peritoneal dialysis system) adapted to direct a certain quantity of fluid from a series of containers (S1, S2, G1, M1, M2) to a patient

The subject-matter of claim 1 differs from this disclosure in that the automatic peritoneal sampling system comprises multiple sampling containers and the series of valves are used to fill each of these containers.

In view of said difference, the subject-matter of claim 1 is new and meets the requirements of Article 33(2) PCT.

The differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis.

None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analysed.

Therefore, the subject-matter of claim 1 involves an inventive step and the claim meets the requirements of Article 33(3) PCT.

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CH03/00048

The automatic peritoneal sampling system disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met as well.

Claims 2 to 24 depend from claim 1 and refer to further embodiments of the automatic peritoneal sampling system described in claim 1 or a peritoneal dialysis system containing the automatic peritoneal sampling system of claim 1. Thus, claims 2 to 24 meet the requirements of Articles 33(2), (3) and (4) PCT for the same reasons explained above.

Nº5905 P CH0300048

5

Claims

1. Automatic peritoneal dialysis sampling system adapted to automatically sample at specific time intervals volumic fractions of a dialysate contained in the peritoneum of a patient in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient, said peritoneal dialysis sampling system being characterized by the fact that it comprises a series of sampling containers, pumping means and a series of valves adapted to direct a certain quantity of each fluid sample to a specific sampling container.

15

10

2. Peritoneal dialysis system comprising an automatic peritoneal dialysis sampling system according to claim 1, a supplying line and supplying means for supplying dialysis fluid to a peritoneal cavity, a draining line, draining means for draining the fluid from said peritoneal cavity, connecting means for allowing a connection to a Y-site on the draining line which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system.

25

20

3. Peritoneal dialysis system according to claim 2 comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.

30

- 4. Peritoneal dialysis system according to claim 2 or 3 comprising means for allowing the use of different peritoneal dialysis liquids and/or different concentrations for each exchange cycle.
- 5. Peritoneal dialysis system according to any of the previous claims 2 to 7 comprising means for allowing the automatic sampling during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle.

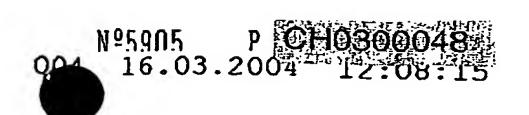
35

10

15

20

25



- 6. Peritoneal dialysis system according to any of the previous claims 2 to 5 wherein said valves are of electromagnetic type.
 - 7. Peritoneal dialysis system according to any of the previous claims 2 to 6 wherein said pumping means is of a peristaltic type.
 - 8. Peritoneal dialysis system according to any of claims 2 to 4 comprising connecting means for connecting it to the draining line between the draining means and a waste collector in order to collect samples of specific drain cycles.
 - 9. Peritoneal dialysis system according to any of the previous claims 2 to 8 furthermore comprising means for eliminating a volume of liquid between two samplings at least equivalent to the dead volume contained between the patient and the sampling level.
 - 10. Peritoneal dialysis system according to any of the previous claims 2 to 9 furthermore comprising an automatic peritoneal dialysis exchange system, both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system being connected to the patient peritoneum and comprising means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.
- 30 11.Peritoneal dialysis system according to the previous claim wherein both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are adapted to be synchronized between each other.
- 12. Peritoneal dialysis system according to any of the previous claims 2 to 11 wherein it comprises a memory key which contains all the necessary data

AMENDED SHEET

10

20

25

30

35



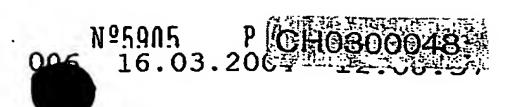
- to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.
 - 13. Peritoneal dialysis system according to any of the previous claims 2 to 12 wherein sampling containers consist of soft pouches.
 - 14. Peritoneal dialysis system according to any of the previous claims 2 to 12 wherein the sampling containers contain vacuum in order to draw the liquid automatically when in open connection with the drawing line.
- 15. Peritoneal dialysis system according to any of the claims 2 to 12 furthermore comprising means for sequentially collecting sample volumes in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.
 - 16. Peritoneal dialysis system according to any of the previous claims 2 to 15 wherein said sampling containers are enclosed inside a cooling box which comprises cooling means to maintain the samples in optimal condition for storage until analysis.
 - 17. Peritoneal dialysis system according to any of the previous claims 2 to 16 comprising analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means.
 - 18. Peritoneal dialysis system according to the previous claim wherein said analyzing means allows the measurement of at least one of the following constituents or characteristics: glucose, urea, creatinine, Sodium, Chloride, albumine, proteins, osmolarity or ph.

10

25

30

35



- 19. Peritoneal dialysis system according to any of the previous claims 17 or 18 comprising means which use the result of the in-line analysis to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a specific patient.
 - 20. Peritoneal dialysis system according the previous claim comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.
- 21. Peritoneal dialysis system according to any of the claims 2 to 20 comprising means for using different peritoneal dialysis liquids and/or different concentrations for each exchange cycle, whether it is a tidal exchange or a full exchange cycle.
- 22. Peritoneal dialysis system according to any of the previous claims 2 to 21 comprising means for allowing the automatic sampling to occur during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a specific patient.
 - 23. Peritoneal dialysis system according to any of the claims 2 to 22 comprising means for eliminating a volume of liquid at least equivalent to the dead volume contained between the patient and the sampling level between two samplings.
 - 24. Peritoneal dialysis system according to any of the claims 2 to 12 and 15 to 23 comprising means for sequentially collecting the sampling volumes in a tubing and for separating each sample from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.